

JOSEPH H. HUNT  
Assistant Attorney General, Civil Division  
ADAM A. REEVES (NYBN 2363877)  
Attorney for the United States, Acting Under  
Authority Conferred by 28 U.S.C. § 515  
SARA WINSLOW (DCBN 457643)  
Chief, Civil Division  
450 Golden Gate Avenue, Box 36055  
San Francisco, California 94102  
Telephone: (415) 436-6925  
Facsimile: (415) 436-6748  
E-mail: [sara.winslow@usdoj.gov](mailto:sara.winslow@usdoj.gov)

ANDY MAO  
JAMIE YAVELBERG  
EDWARD CROOKE  
Attorneys, Civil Division  
P.O. Box 261  
Ben Franklin Station  
Washington, D.C. 20044  
Telephone: (202) 353-0426  
Facsimile: (202) 514-0280  
E-mail: [edward.crooke@usdoj.gov](mailto:edward.crooke@usdoj.gov)  
Attorneys for the United States of America

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, <u>ex rel.</u>	)	CASE NO. C-11-0941 EMC
CAMPIE,	)	
Plaintiff and Relators,	)	<b>UNITED STATES' SECOND</b>
v.	)	<b>SUPPLEMENTAL FILING IN SUPPORT</b>
GILEAD SCIENCES., INC.,	)	<b>OF ITS MOTION TO DISMISS</b>
Defendant.	)	<b>RELATORS' SECOND AMENDED</b>
	)	<b>COMPLAINT</b>

1 Pursuant to 31 U.S.C. § 3730(c)(2)(A), the United States moved to dismiss this action  
2 based on its determination that further litigation will impose monitoring costs and discovery  
3 burdens on the government that are not justified. The Relators opposed the motion, and the  
4 Court conducted a hearing on August 1, 2019. After the hearing, Relators' counsel contacted the  
5 United States to propose narrowing the claims they would pursue in this action to drugs  
6 produced at Gilead's Foster City facility using specific lots of active pharmaceutical ingredient  
7 (API) sourced from Synthetics China. Third Crooke Decl. at ¶ 2. On August 7, 2019, Mr.  
8 Friedman documented Relators' proposal in an email to government counsel. Id. The Court  
9 conducted a second hearing on September 24, 2019, and asked whether the government had  
10 considered Relators' offer to narrow their claims. See Tr., ECF 239, at 6:18-21 ("But what about  
11 the offer that the Relator made to limit this FCA claim to the specific batch of impurities or  
12 adulterated drug products in the Foster City facility in late 2011, early 2012 that led to the  
13 issuance of a Form 483?"). In particular, the Court asked the United States to memorialize its  
14 representation during the hearing that government counsel consulted with representatives of the  
15 Department of Health and Human Services (HHS) regarding Relators' proposal. See ECF 239 at  
16 11:21-24 ("Would you be prepared to put in the record your representation to the Court, but in  
17 the form of a declaration, about this consultation with the FDA and the Inspector General and the  
18 Chief Counsel and all that?"). The United States makes this supplemental filing to address those  
19 questions and also to address a separate question regarding the frequency with which the United  
20 States has sought dismissal pursuant to Section 3730(c)(2)(A).

21 The lots identified in Mr. Friedman's proposal were the subject of Field Alert Reports  
22 that Gilead submitted to the Food and Drug Administration (FDA) between November 2011 and  
23 January 2012 to disclose the presence of particulates in finished drug products at Gilead's Foster  
24 City facility. Scavdis Decl., ECF 185, at ¶ 5; Weiner Decl., ECF 201, at Ex. 13. In March 2012,  
25 FDA requested additional information about validation and reprocessing of batches of API  
26 manufactured at Synthetics China, and received additional information from Gilead in April  
27 2012. ECF 185 at ¶ 6. In June 2012, FDA conducted an on-site inspection of the Foster City  
28 facility and issued a Form 483. Id. at ¶ 5. Gilead responded to the Form 483 on July 30, 2012.

1 ECF 201 at ¶ 36 & Ex. 13. After considering Gilead's Field Alert Reports, obtaining  
2 supplemental information, conducting an on-site inspection, and reviewing Gilead's response to  
3 the Form 483, FDA did not stop production at Synthetics China, Foster City, or any other Gilead  
4 manufacturing facility, and FDA did not determine that any of Gilead's drug products needed to  
5 be recalled. ECF 185 at ¶ 7. This information was all known to the United States when it  
6 determined not to intervene in this case in January 2013.

7 On August 12, 2019, government counsel forwarded Mr. Friedman's email to  
8 representatives of the HHS Office of General Counsel (including the CMS Division and the FDA  
9 Office of Chief Counsel) and the HHS Office of Counsel to the Inspector General. Third Crooke  
10 Decl. at ¶ 3. On August 15, 2019, government counsel spoke by telephone with these HHS  
11 representatives and discussed, among other things, whether Relators' proposal altered their  
12 assessment of the potential for a monetary recovery or the costs to the government of the case  
13 proceeding. Id. HHS continued to recommend pursuing dismissal. Id.

14 At the September 24, 2019 hearing, the Court also asked whether the Department of  
15 Justice was permitting relators in other *qui tam* actions to pursue cases when it has not  
16 intervened. See ECF 239 at 26:8-11 ("Are cases being allowed to go forward where the  
17 Government has refused to intervene? . . . I don't mean years ago. I mean now."). In Fiscal  
18 Years 2018 and 2019 (Oct. 1, 2017 to Sept. 30, 2019), relators filed approximately 1,274  
19 complaints pursuant to the *qui tam* provisions of the False Claims Act. Third Crooke Decl. at ¶  
20 4. In those two years, the United States intervened or partially intervened in approximately 218  
21 *qui tam* complaints (some of which had been filed before October 2017). Id. On January 10,  
22 2018, then-Director Michael Granston issued a memorandum to AUSAs and attorneys in the  
23 Commercial Litigation Branch on Factors for Evaluating Dismissal Pursuant to 31 U.S.C.  
24 3730(c)(2)(A). The Department incorporated the substance of the memorandum into Section 4-  
25 4.111 of the Justice Manual. Since January 10, 2018, the United States has moved to dismiss  
26 approximately 36 cases pursuant to Section 3730(c)(2)(A) (some of which had been filed and/or  
27 declined before January 10, 2018). Id.

Respectfully submitted,

JOSEPH H. HUNT  
Assistant Attorney General

ADAM A. REEVES  
Attorney for the United States, Acting Under  
Authority Conferred by 28 U.S.C. § 515

Dated: October 8, 2019

By: /s/\_\_\_\_\_  
SARA WINSLOW  
Assistant United States Attorney

Dated: October 8, 2019

By: /s/ *signature on file*\_\_\_\_\_  
EDWARD CROOKE  
Civil Division, Fraud Section  
Attorneys for the United States of America